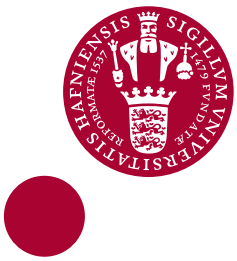

A totally new system is needed for drug research and development

Gøtzsche, Peter C.

Published in:
European Journal of Clinical Investigation

DOI:
10.1111/eci.12883

Publication date:
2018

Document version
Publisher's PDF, also known as Version of record

Received: 19 December 2017 | Accepted: 19 December 2017

DOI: 10.1111/eci.12883

LETTER TO THE EDITOR

WILEY

A totally new system is needed for drug research and development

In response to my paper,[1] where I call for abolishment of patents and for drug research and development as a public enterprise, Raj asserts that there is an increase in novel drug discoveries. The fact is that even the drug industry laments that drug innovation has dried out, which is why they buy start-up companies. Big Pharma doesn't invest in innovative research, as it is far more profitable to have creative marketing and legal departments than creative research divisions and to develop an endless array of "me too" products.[2]

I referred to France because *Prescrire* is one of the very few journals where none of the editors or authors are allowed to have conflicts of interest in relation to the drug industry.[2] The French results have global value, as the drug market is global, and I believe it is clear that I have tried to address the global problems we are facing with development, pricing and usage of drugs and not only those in high-income countries. Since 1981, *Prescrire's* Pilule d'Or (Golden Pill) has been granted to drugs that constitute a major therapeutic advance in a field in which no treatment was previously available. There was no worthy candidate for 1982, 1984, 1985, 1990, 1991, from 1993 to 1995, for 1997, from 1999 to 2005, from 2008 to 2013, and for 2015.[3]

The statement by Raj that novel drugs for infectious diseases come second after cancer drugs among new FDA approvals is not reassuring. Everywhere, people complain about antibiotic resistance and the lack of innovative antibiotics,[4,5] and no matter how many "novel" drugs FDA has approved, the clinical situation has not improved during the last 20 years. Patients die in huge numbers because we do not have effective antibiotics against tuberculosis, methicillin-resistant staphylococci, beta-lactamase-producing *E. coli*, carbapenemase-producing organisms and so forth. The paper Raj refers to only says that 14% of the novel drugs were for infections, not whether these drugs were antibiotics, immunoglobulins, vaccines, or something else, or whether they were simply "me too" drugs with no added value.[6] It is similarly misleading when Raj praises progress against cancer because extremely few cancer drugs add anything of value.[7]

Raj asserts that around half of the newer drugs were approved for acute and intermediate disease conditions and argues that this contradicts my statement that the industry tends to focus on drugs to treat chronic conditions that affect many people. Raj seems to have a naive view about what the drug industry does and why. Illegal marketing is one of the most common and profitable crimes the drug industry commits,[2] and many drugs that should only have been used short-term end up being used for life, for example psychiatric drugs, although the long-term use of these drugs causes vastly more harm than good.[8,9]

Raj believes I underestimate the importance of adaptive trial designs. These designs allow drugs to be approved based on observational data only, which is a disaster for public health.[10] Our drugs are already the third leading cause of death after heart disease and cancer,[2,9] and the lowering of regulatory standards for new cancer drugs and other drugs has increased the rate of drug withdrawals because of safety issues[2] and has undoubtedly increased the death toll further.

Considering all the unnecessary deaths we cause with drugs most people don't really need,[2,9] we must require that trials submitted for obtaining marketing authorization are large enough and have run for sufficient lengths of time to capture rare but lethal harms and we should avoid approving drugs based on surrogate outcomes. We do not approve cars based on the fact that we can start the engine. We require more than this, in particular safety studies. But with drugs, which kill about 10 times more people in my country than cars do, we do not care that we have not requested adequate safety data.[2] This is insane.

Raj argues for a holistic approach where nondrug and drug therapies complement each other rather than considering them as mutually exclusive components. Fine, but first we must stop the lethal drug epidemic, which means using drugs far less than we do today. Whenever we can, we should prefer nondrug therapies, as they don't kill people.

[The copyright line for this article was changed on 25 July 2018 after original online publication.]

Raj misquotes me when he asserts that I was not the first to envision a future without patents. Of course, I wasn't but in the working group I participated in, I coined the idea of a future without patents and with public development of drugs.[1] The chair found these ideas far-fetched and became very surprised when it turned out that 10 of the 30 invited people were willing to join me.

ORCID

Peter C. Gøtzsche http://orcid.org/0000-0002-2108-7016

Peter C. Gøtzsche
Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark

Correspondence
Peter C. Gøtzsche, Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark.
Email: pcg@cochrane.dk

REFERENCES

1. Gøtzsche PC. Patients not patents: drug research and development as a public enterprise. *Eur J Clin Invest*. 2018;48:e12875.
2. Gøtzsche PC. *Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Health Care*. London: Radcliffe Publishing; 2013.
3. Pilule d'Or/Golden Pill 1981-2016. http://english.prescrire.org/en/115/727/52691/5143/5132/SubReportDetails.aspx.
4. Nathan C. Antibiotics at the crossroads. *Nature*. 2004;431:899-902.
5. Morel CM, Mossialos E. Stoking the antibiotic pipeline. *BMJ*. 2010;340:c2115.
6. Downing NS, Aminawung JA, Shah ND, Krumholz HM, Ross JS. Clinical trial evidence supporting FDA approval of novel therapeutic agents, 2005-2012. *JAMA* 2014;311:368-77.
7. Wise PH. Cancer drugs, survival, and ethics. *BMJ*. 2016;355:i5792.
8. Whitaker R. *Anatomy of an Epidemic*. New York, NY: Broadway Books; 2015.
9. Gøtzsche PC. *Deadly Psychiatry and Organised Denial*. Copenhagen: People's Press; 2015.
10. Davis C, Lexchin J, Jefferson T, Gøtzsche P, McKee M. "Adaptive pathways" to drug authorisation: adapting to industry? *BMJ*. 2016;354:i4437.